UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DANA-FARBER CANCER INSTITUTE,)
)
Plaintiff,)
)
) No. 1:10-cv-11613-DPW
vs.)
)
GATEKEEPER PHARMACEUTICALS,)
INC., ET AL,)
)
Defendant.)

BEFORE: THE HONORABLE DOUGLAS P. WOODLOCK

MOTION HEARING

John Joseph Moakley United States Courthouse
Courtroom No. 1
One Courthouse Way
Boston, MA 02210
Wednesday, January 11, 2012
2:30 p.m.

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(The following proceedings were held in open court before the Honorable Douglas P. Woodlock, United States District Judge, United States District Court, District of Massachusetts, at the John J. Moakley United States Courthouse, One Courthouse Way, Courtroom 1, Boston, Massachusetts, on Wednesday, January 11, 2012):

THE CLERK: All rise.

(The Honorable Court entered the courtroom at 2:30 p.m.)

THE CLERK: This Honorable Court is now in session. You may be seated.

This is Civil Action 10-11613, Dana-Farber Cancer Institute versus Gatekeeper Pharmaceuticals.

Will counsel please identify themselves for the record.

MR. BRASHARES: William Brashares for Dana-Farber Cancer Institute.

MR. SCOTT: Good afternoon, your Honor. Timothy Scott. With me also in the courtroom is John Chant, CEO of Gatekeeper, and Ted Folkman.

MS. PIROZZOLO: Lisa Pirozzolo from Wilmer Hale for Novartis, and with me is Heather Price. Dr. Barish Ozdamar has passed the bar in New York but is not admitted yet. Does your Honor mind if he sits at counsel table?

THE COURT: No. You vouch for him. We know where to find you.

MS. PIROZZOLO: Thank you, your Honor.

THE COURT: Is he going to have a speaking part?

MS. PIROZZOLO: No.

THE COURT: Well, I kind have had the feeling that there were ships passing in the night as I went through the briefing in this case, and I struggled to try to figure out how to focus the issues here.

I think, at least at the outset, it turns on the question of what "in part" means in this context, and the parties do not seem to have a theory of that, at least one that is grounded for me. The Gatekeeper approach seems to be intensely fact-based, which is helpful, but there has to be a theme to that pudding, and the Novartis approach is -- perhaps it is too much to call it ethereal, but it does not really grab the issues carefully, from my perspective.

So, I guess I would like to start by just understanding what the parties think "in part" means as a definition or almost a matter of construction in this setting.

So, maybe, Ms. Pirozzolo, I will start with you.

MS. PIROZZOLO: Yes, your Honor. Well, of course "in part" is in the definition of "program technology," and we believe it means what it says, that the definition of "program technology" covers technology invented, discovered or developed in whole or in part by the Institute Program participant, which is --

THE COURT: And are conceived or reduced to practice as part of a Funded Research Project.

MS. PIROZZOLO: That's correct.

THE COURT: Both features have to be present. But what does that mean? I can use a homely analogy, just to perhaps structure it a bit, by saying the man who gives you the map to Treasure Island is probably within "in part;" the guy who tells you that Treasure Island is in Michigan probably is not, or at least I would think so, unless everything that touches it is "in part".

So, how do I draw the line? It means what it says. All right. This is like saying, "The document speaks for itself," and I look down at the document and say, "All right, talk to me, document."

(Laughter)

MS. PIROZZOLO: Well, I can tell you how we interpret the phrase in a way that is relevant to this case. Dr. Eck is a coinventor of the patent application at issue, so he is clearly an Institute Program participant. So, the invention here was clearly invented, at least in part, by Dr. Eck, because is a coinventor of the patent.

THE COURT: But so what? Is he tainted. Is there a bill of attainder that attaches to him for whatever he does? Then I guess we focus on the question of what it means to conceive and reduce to practice as part of the funded research

project.

MS. PIROZZOLO: And I think that's exactly right. So, our position is that Dr. Eck and Dr. Gray were both program participants. So, clearly the invention was invented, discovered or developed at least in part by people obtaining funding from Novartis, and our position is -- and I am happy to walk through it; we have prepared slides which I hope aren't ethereal and I hope are focused -- that the invention was certainly conceived as part of a funded research project, and I'm happy to walk through --

THE COURT: I am going to go to that in a minute, but I want to just seize the first part of that, and that is that if an Institute Program participant participates in the invention or the discovery or the development, then the "in part" is met; is that it?

MS. PIROZZOLO: Yes. Well, the "in part", yes, that part of the phrase, and then you have the second part of the definition that has to be conceived.

THE COURT: And I will get to that. So, back to my attainder analogy, that it is an attainder. Once you have got a program, Institute Program participant, anything that you are involved in that touches on invention and discovery and development is included in "in part"?

MS. PIROZZOLO: If it means the latter part of the definition as well.

THE COURT: But we will do it in two parts.

MS. PIROZZOLO: Yes, your Honor.

THE COURT: So, let me take it a bit further. The individual who is an Institute Program participant is drawn into this no matter how minimal his role in the invention or the discovery or development is, right?

MS. PIROZZOLO: Well, he is drawn into the first part of the definition only, yes.

THE COURT: All right. In for a dime, in for a million dollars.

MS. PIROZZOLO: It means you are going to look at the second part to see if that person played a role in conception or reduction to practice.

THE COURT: Now, let me just stop and see whether Gatekeeper has any refinement to that.

MR. SCOTT: I think that there are two prerequisites to this being program technology. The first is a program participant participate in the invention. So, in that sense I agree "in part" --

THE COURT: All right. I just want to be sure.

MR. SCOTT: Sit down?

THE COURT: Nothing personal, but I just want to move on to something that may be disputed.

So, now we come to the conceiving or reducing to practice as part of the funded research project, and here don't

I have to look at when it is that it is reduced to practice, I mean the temporal occasion upon which it is reduced to practice?

MS. PIROZZOLO: Well, your Honor, the definition says conceived *or* reduced to practice. So, I think you look at --

THE COURT: I am interrupting you, and you will have different views of their material, but conception and reduction to practice are almost the same thing in respect of this particular technology, aren't they?

MS. PIROZZOLO: I don't agree, your Honor, and I'm happy to -- we cited, I believe, in our brief conception is the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention, and the Burroughs Wellcome case, which actually Gatekeeper cited, specifically says that an inventor need not know that his invention will work for conception to be complete.

THE COURT: But conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties or whatever characteristics sufficiently distinguish it, which is to say, in this context pretty close to reducing it to practice. Yes, there is an idea. Between the idea and the reduction passes a shadow, but it is a relatively narrow shadow, I think.

MS. PIROZZOLO: Well, here, just the patent

application, if you look at Claim 1 of the application, it is what's called the genus claim, so it includes millions of compounds. It's got a form chemical structure and that is what Dr. Eck conceived, that basic structure of a compound when he did his crystallography studies. He said, We want to make irreversible inhibitors that bind to a particular cysteine on certain kinases, and that's what that class represents.

THE COURT: All right. But the question is, when do we have conception and reduction to practice? That is, I guess, what I am getting at. Is there a broad time period?

MS. PIROZZOLO: Well, clearly --

THE COURT: You say 2007, I guess.

MS. PIROZZOLO: Well, Dr. Eck did his -- and I'm happy to walk through the chronology, reciting to the record -- but Dr. Eck did his studies on QAD-409 and Jak3 and another inhibitor, an EGFR, and he superimposed those crystal structures, and that's where he got his idea of making this class of compounds.

THE COURT: Isn't the real point for conception and reduction to practice -- because I still do not distinguish between them materially here -- isn't the real point when someone discovers the connection between the synthesis of WZ-4002 and its effect on the T790M mutation? Isn't that the point?

MS. PIROZZOLO: Your Honor, this is a really

fundamental point that I want to be clear on. No, we do not think that's the issue in the case, because the claims -- there is a fundamental disconnect, if anywhere, on the scope of the patent application that's at issue. This patent application does not contain one claim to that particular compound. That is the lens through which -- if there are ships passing in the night, that's why, because they say the IP is that compound and the knowledge that that compound inhibited the Gatekeeper mutation selectively.

THE COURT: So, let us go to some sort of "but-for" analysis. If I were dealing with this and saying this is not an agreement, this is an infringement, let us say that you have some intellectual property that you can claim. I think I probably would say about the only claim you have of infringement is 51. That is about the only one that gets into this kind of use of WZ4-002 and T790M, right?

MS. PIROZZOLO: I don't think so, your Honor. The Claim No. 1 is a broad genus claim that includes --

THE COURT: So, you say if it is a genus claim we get everything that we can, even if it is not identified with some specificity with respect to this kind of conception and reduction to practice?

MS. PIROZZOLO: Well, what you have in the patent, just to be clear, is, you have the genus claim. That's Claim 1. That's very broad, millions of compounds, clearly not

limited to WZ-4002.

THE COURT: But why shouldn't I limit it to that? That is what you brought to the table, or that is what you had in the mix. Otherwise, and I will put this in a different way, for public policy purposes you would be substantially reducing the -- maybe proliferating a number of patent claims, one that does precisely what you ask for and then one that asks for everything else that is in the genus.

MS. PIROZZOLO: Just to be clear, your Honor, the context in which this arises is Novartis didn't file the patent application.

THE COURT: No, I understand that. So, what I am asking is I guess a more specific question about distorting the application process for these kinds of claims. Now, one way of looking at it is this is kind of a "gotcha." They make, on your theory, a genus claim and you say, Well, on this one too, in for a dime, in for a million dollars.

MS. PIROZZOLO: I don't think it's a "gotcha," your Honor, because if the funded research led to a broad class of inhibitors that was then claimed by the applicants in a patent application that was filed, under the contract we had an option right to that patent application. If they wanted to claim it narrowly, then I guess that would be a different case, but that's not what we are here about. The patent application that was filed is a very broad class of compounds.

And I want to say, just to be clear, we don't agree that Novartis funding had no role in the compound WZ-4002, because we believe that the record shows that the crystallography structures that Dr. Toms was doing in Dr. Eck's lab that were being exchanged with Dr. Gray's lab that Dr. Zhou was using to make the different compounds in Spring of 2007, that was Novartis-funded research. So, we disagree with the concept that --

THE COURT: But the issue goes back for me, on this aspect of it, to conception and reduction to practice. So, maybe they were working in this area, but we have to get to the point of reduction to practice.

Let me just move off this, because you had mentioned why we are here, and I want to be sure I understand why we are here.

Let me assume for a moment, just to test this, that you are correct and you have disclaimed on this. What happens then? Basically they take it but you do not have any damages, or are you suggesting that your right to this patent means that you can prevent them from being involved in practicing this invention?

MS. PIROZZOLO: I think there is a fundamental confusion here. The only claim that Novartis is facing in this case is as a defendant. We are being accused of tortiously interfering --

THE COURT: No, I understand that.

MS. PIROZZOLO: -- with Gatekeeper. So, we have washed our hands of this. If you rule that we were entitled to it, then summary judgment enters for us on the claim. We are not going to obviously assert the claims, because we have waived the right to license it. So, it's now Gatekeeper's claim.

THE COURT: Then it passes, under your theory, to the next level of priority?

MS. PIROZZOLO: Yes. As I understand it, Dana-Farber has given Gatekeeper rights to the patent application and Novartis is no longer involved with it.

THE COURT: Now, let me go back to this set of issues, and I am trying to think of this in terms of maybe "but for" as a way of dealing with it. It takes a village to raise a child, but "conception" tends to be a narrower transaction. So, I am focusing on that point of conception, or what I concede to be that point of conception, and I want to understand from you where you say that is, when you say that is.

MS. PIROZZOLO: I say it was when Dr. Eck and Dr. Gray met and decided to make this class of compounds based on the QAD-409 scaffold, and that occurred -- no one had an exact date -- but sometime in late 2006.

THE COURT: And so, merely holding hands is conception, to keep the metaphor?

MS. PIROZZOLO: Well, what Dr. Eck said is that basically once he -- and I should say this kind of moved along. So, they had the first conversation and then they kept talking and collaborating during 2007. So, maybe conception of the broad genus occurred at an earlier time than conception of some of the other more specific claims, but that is when Dr. Eck said those crystal structures that he had developed could be used to design inhibitors that had particular features, irreversible inhibitors with particular features that would bond with the cysteine in the vicinity of the ATP binding pocket.

I would note that Gatekeeper essentially describes the invention as those structures that would bind -- I think it's at page 7 of their brief; I'm looking for the reference -- but that bind to the cysteine in the vicinity of the ATP binding pocket. So, once you had the idea to do that --

THE COURT: Well, but isn't it more than simply binding? It is also some concept of displacing, for purposes of binding, a different way of binding there, and have they conceived that in 2007?

MS. PIROZZOLO: Yes, your Honor. Because if you look at Dr. Eck's May 2007 presentation to Novartis describing his research -- and I'm happy to put it up. I brought a presentation slide.

THE COURT: Go ahead.

MS. PIROZZOLO: It's slide 26. Okay. So, Dr. Eck was doing a presentation to Novartis in May --

THE COURT: Is this us or you that is causing the --

MS. PRICE: I think it's on the monitor.

THE COURT: I am seeing movement on the monitor. If it is us, we will get somebody from IT to fix it.

MS. PIROZZOLO: I think it's you, because it's not moving on our computer. I don't know if you have the exhibits, your Honor.

THE COURT: I do.

MS. PIROZZOLO: It's Exhibit 90. And you can see on the cover page it's a presentation. Actually, your Honor, I have a hard copy of our presentation, so maybe I can use that.

So, your Honor, it's page 26 in the presentation I just handed up, but it is also Exhibit 90 in the book.

THE COURT: I have got it now.

MS. PIROZZOLO: And these are conclusions that Dr. Eck stated, and just for context, this is a presentation Dr. Eck gave to Novartis, and he talks about the increased affinity of -- he talks about two mutants of EGFR, L858R and T790M for ATP is a major factor in inhibitor resistance. So, he discovered that.

And then he has a second conclusion which I think directly goes to your point, that, "Irreversible inhibitors, as a class, overcome resistance through covalent binding."

So, he has stated the rationale for the design of this particular class of inhibitors. And if you look earlier in the presentation, and this is at page 19 of the presentation, he specifically has the structure of, he has his --

THE COURT: Page 19?

MS. PIROZZOLO: Page 19, your Honor. You can see a picture in the presentation where Dr. Eck puts his co-crystallization studies there, and that's the figure on the left-hand side of the page, and that is a picture of EGFR and 13-JAB, that's an inhibitor, superimposed on a co-crystallization of Jak3 and the Novartis inhibitor QAD-409. And he is pointing out on the right-hand side of the page what this teaches me is the active site of binding is this particular cysteine that's in both of these kinases. And then he has the figure of QAD-409, the chemical structure there.

And what he testified, he suggested to Dr. Gray was, Why don't we use this scaffold, they call it, as a basis for designing chemical compounds so that we can create irreversible inhibitors for these kinases?

So, I put on the slide his deposition testimony: "So, we had determined that both Jak3 QAD-409 complex structure, and also, the...EGFR in complex...", so that they both have the Cysteine in this equivalent position.

And then when I asked Dr. Eck at his deposition what he was trying to portray in this slide, he said, "So...using

structural modeling, this structural superposition basically showed us sort of where one would want to attach the irreversible warhead on this alternate scaffold QAD409 or something like it, in order to efficiently react with the target Cysteine to make an irreversible inhibitor."

So, he is doing much more than having an abstract idea of compounds. He is figuring out why he wants to make the compounds he wants to make, he's actually suggesting a particular scaffold to use, QAD-409, and that is precisely what he told Dr. Gray about and gave to Dr. Gray, and Dr. Gray's lab then went ahead and made compounds based on the scaffold, and those very same compounds are claimed in the patent application.

So, we don't think it's just an abstract -- I forget the phrase Gatekeeper used -- an "inspiration." It's much more than an inspiration. This is a very specific guideline.

And, in fact, another way to think about it is, Dr. Eck is a coinventor on this patent. Gatekeeper's story of the invention doesn't really acknowledge any role he played. His role, as he explained it, was coming up with the idea based on co-crystallization studies that his lab was uniquely expert in to make these types of compounds.

And so, to get to EGFR, if you look at page 20 of our presentation, Dr. Eck also clearly explained why his work on Jak3 was relevant to work on EGFR. Those two compounds, as you

can see from his superimposed structure, have common characteristics. Both have, and he testified to this and the quote is on page 20, a Methionine gatekeeper, as does the gatekeeper mutation of the EGFR. So, he says, "...irreversible inhibitors of Jak3, may also be good irreversible inhibitors of the T790 mutant of EGFR by virtue of the fact that both have the same cysteine and also a methionine gatekeeper residue."

So, he was doing studies on EGFR, the Gatekeeper mutant, he was also doing co-crystallization studies with QAD-409. He is the one, and this is on page 21 of our presentation, who shared that modeling with Dr. Gray. He testified, "...the modeling that we did and that we shared with Nathanael was based on looking at the co-crystal structure of QAD409 with Jak3, superimposed on an EGFR structure in complex with an irreversible inhibitor, the 13-jab compound..." And then he says, "that basically...became an exercise in, you know, add this chemical group to...this scaffold in roughly this position."

So, he was the one that was the mastermind of creating this class of compounds.

And so, he explains how he met with Dr. Gray in his office and explained this strategy to him, "...explained the strategy which was obviously immediately obvious to him, and expressed my interest in collaborating with him in developing these irreversible inhibitors based on these and potentially

other scaffolds using this sort of strategy...informed by our, at that time, unpublished structures of Jak3 with QAD-409 and with EGFR with irreversible Parke-Davis inhibitor."

So, to get to your Honor's question about a "but-for" analysis, the compounds that Dr. Gray's lab made in 2006 and 2007 originated with Dr. Eck and his Novartis-funded research on co-crystallization studies.

And if you look at the next slide in our presentation, that's slide 22, Dr. Zhou, who is the person that made all these WZ compounds, his name is Wenjun Zhou, testified, "I saw this crystal structure with QAD-409 as our basis for designing the new compounds." So, he was given the co-crystallization structures that Dr. Eck had told Dr. Gray about, and he used that idea and those structures to make the WZ compounds.

And if you turn to the next slide, your Honor, slide 23, you can see an example of one of the compounds Dr. Zhou made. So, I have put the NVP-QAD-409 on the left-hand side of the slide and then the WZ-1-84 compound on the right, and you can see how similar the structures of those compounds are, because Dr. Zhou used those compounds to inform -- used the idea Dr. Eck had given about starting with QAD-409 to make compounds.

And I would just like to, if I could, address something that Gatekeeper raises in its brief, which is, well, WZ-1-84 has no bearing on this case, there are different kinds

of compounds that are at issue here. Compounds that look just like WZ-1-84 are right in the patent application. If you look, for example, at Table 1 of the patent application -- and I don't know if you're able to toggle between slides, but we have Table 1 at page 7 -- the compound that is in the patent application as compound number 1-3 is virtually -- it's very similar to WZ-1-84. The only difference is, if you look at the compound 1-3 there is a chlorine addition in the top right-hand side, a little line going off. That's the only difference between the WZ-1-84 and the compound claimed in the patent application.

So, it's very clear that Dr. Eck conceived of the general idea of making this class of compounds and was the one who communicated that idea to Dr. Gray, who in turn communicated it to Dr. Zhou, who made the compounds, and then they tested these compounds.

And I don't know if your Honor would like me to go on to reduction to practice, but it's clear that --

THE COURT: Yes, I do.

MS. PIROZZOLO: -- that these compounds were --

THE COURT: I do want you to reduce it to practice.

MS. PIROZZOLO: Okay. So, Gatekeeper's position is that the compounds were not reduced to practice until Fall of 2008, when Dr. Janne did certain tests. But there is evidence, your Honor, undisputed evidence, that compounds that were in

this class that Dr. Zhou made, as suggested by Dr. Eck, had already been shown to be inhibitors of kinases.

So, if you look at Dr. Gray's -- and we try to explain this with reference to Dr. Gray's own grant application to the National Science Foundation in July of 2007. It's at page 27 of our presentation. So, this is in July of 2007, so long before Fall of 2008, obviously, Dr. Gray submits this application, and the key pages of that are DFC 4917 to 73. Basically there Dr. Gray explains how he used the crystal structures of Jak3 and QAD-409 as the basis for developing irreversible inhibitors, and he not only explains the rationale for making that class of inhibitors but also provides data showing some of the inhibitors were effective. Does he provide data for WZ-4002? No, but he provides data for inhibitors in the class.

THE COURT: I have let you go on for a bit without asking some questions, but I compare that to his, Dr. Gray's, annual report in connection with this Novartis funding, and if we are thinking of this as being the point at which it was reduced to practice in his 2007 annual report, he says, A couple of scaffolds also inhibit the Gatekeeper mutant of basically T790M, showing that the approach is general, but he says, This will serve as a good starting point. He does not talk about it as a reduction to practice in addressing Novartis. So, maybe it is possible to distinguish between

conception and reduction to practice, but reduction to practice does not appear, at least from Dr. Gray's perspective, to be in 2007.

MS. PIROZZOLO: Well, what Dr. Gray says that refers to is a completely different project from the project that's described in the National Science Foundation application. He says that was not related.

THE COURT: Well, I guess he does. On the other hand, I am not sure what significance I attach to the *post hoc* characterization of something that he said earlier, and he said that he was not focused primarily on using the rational design to prepare selective inhibitors. So, we are at a point at which we are before reduction to practice, at least by the language that he is using, and the language that he is using captures the reduction to practice of this invention, even as broadly conceived as you have it.

MS. PIROZZOLO: Well, has your Honor looked at the -- I'm referring to the National Science Foundation publication.

THE COURT: I know you are, and I am now cross-checking against what Dr. Gray is telling Novartis.

MS. PIROZZOLO: Well, his explanation is that's a different project.

THE COURT: Well, that is the explanation, or assertion is probably closer to it, and the question is how can I reasonably believe that under these circumstances? He says,

okay, that was something else. If it is something else, I cannot see it.

MS. PIROZZOLO: Well, it's very confusing, to be honest, because in the National Science Foundation grant he, for example, has a picture of QAD-409, which is the Novartis inhibitor, that he calls P1 for reasons he couldn't explain at his deposition.

THE COURT: All of that is true, but what I guess we are getting at, without getting too much into the history and also bias under these circumstances, but it is that there was uncertainty at this point, there was not reduction to practice at this point. Even he concedes that.

MS. PIROZZOLO: Your Honor, but he and Dr. Eck both made presentations and disclosed data that had the rationale for making the class of inhibitors, had the actual chemical structures of the inhibitors and showed data to show that those chemical compounds inhibited a variety of kinases. So, under any definition of "conception and reduction to practice" in the Federal Circuit cases, those compounds were conceived and reduced to practice by then. So, what we have shown in the record is --

THE COURT: I do not want to put too much emphasis on various ways before various audiences that Dr. Gray characterizes this, but a good starting point is a reduction to practice under Federal Circuit law?

MS. PIROZZOLO: Well, under Federal Circuit law, the definition of "reduction to practice" is -- I'm flipping in my presentation because we have set out those cases at page 13 -- is, constructs a product or performs a process that is within the scope of the patent, demonstrates the capacity of the invented idea to achieve its intended purpose. And in the pharmaceutical arts it is sufficient, and we are actually using the case Gatekeeper referred to in its brief, the Fujikawa case, any pharmacological activity is sufficient. So, as long as you have data showing inhibition of kinases, which is what the patent is directed to, you have had a reduction to practice.

Gatekeeper wants to say, Well, no, you need to show specific inhibition of the Gatekeeper mutant of EGFR, and you need to show it's selective. That's not the law, as far as the reduction to practice of chemical composition claims; any pharmacological activity is sufficient. And Dr. Gray and Dr. Eck collaborated in making the compounds that fall within the scope of the patent, and they also tested them and showed they had inhibition activity.

THE COURT: Well, let me put it in a different way, then. Is the synthesizing of 150 new-type inhibitors covering approximately 10 distinct scaffold classes sufficient to reduce to practice under this language? I have to say I have not looked carefully at Fujikawa, but it seems a little

latitudinarian in its approach. Any pharmacological activity is a reduction to practice?

MS. PIROZZOLO: Well, it's reduction to practice of the compound claim, if you want to claim the compound, because otherwise it would be confusing as to when the compound claim was reduced to practice. If it wasn't any pharmacological activity would you have endless debates about, well, they showed activity here but it really isn't important and they showed activity there but it really wasn't important?

THE COURT: Well, I do not know why you would not. That just makes synthesis, any kind of synthesis, reduction to practice, any pharmacological activity.

MS. PIROZZOLO: The reason it's important here is right in the patent claims.

THE COURT: Is? I am sorry.

MS. PIROZZOLO: You can see the importance in the patent claims. The patent claims, Claim 1 is this broad genus, Claim 51 is inhibition of any kinase, and then it goes on to get a little more specific to kinases with a cysteine in a certain position. So, if you show inhibition activity in any kinase that falls within the scope of Claim 51, you can't say, Well, no, you needed to show it in the Gatekeeper mutant of EGFR. That would be contrary to what these patent claims are, which is inhibition in any kinase --

THE COURT: Why wouldn't I, then, carve through it and

say, okay, you get so much as where I started earlier, as exists in 51, you do not get more, you do not get less, as a way of cabining this from creeping over every kind of pharmacological activity that these program participants engaged in?

MS. PIROZZOLO: Just to be clear, your Honor, we don't want any of it. All we are trying to show is that we didn't tortiously interfere by virtue of claiming, Hey, we're entitled to license this patent under the CRA. That's the only issue that's relevant to the claims against Novartis.

THE COURT: Well, it may or may not be in the sense that if I limit it to -- I am just saying Claim 51 as a way of carving it out a little bit more carefully, you would still be faced with a question of tortious interference, wouldn't you?

MS. PIROZZOLO: Why is that, your Honor?

THE COURT: Well, I will ask them.

MS. PIROZZOLO: Well, because I feel like if the claims are broad enough to cover the class of compounds --

THE COURT: Let us assume that I say -- I am trying to understand this more fully, and so I say not Claim 1; that is just too broad.

MS. PIROZZOLO: You're saying Claim 1 is invalid?

THE COURT: No, because we are not talking about invalidity here; we are simply talking about what is it that you get to piggyback on. You do not get to piggyback on Claim

1. You do get to piggyback on Claim 51.

MS. PIROZZOLO: Well, then, I think the implication is we should have been asked about that and given the right to exercise our license to Claim 53, and that never happened here, and we certainly didn't tortiously interfere by saying, Hey, you know, we think we may have rights because we funded a lot of research on these subjects at Dana-Farber.

THE COURT: All right. Unless there is something more that you want to say about this aspect --

MS. PIROZZOLO: "This aspect" meaning conception --

THE COURT: -- being conception and reduction to practice.

MS. PIROZZOLO: I think I have covered it, your Honor.

THE COURT: So, let me just see if I have got a couple of the -- I will not call them secondary -- but alternative arguments clear under these circumstances.

I see the assertion that Gatekeeper says that Dr. Gray sought and obtained the Steering Committee's consent with respect to consulting as a consulting agreement. Is that in dispute or not? I could not find the evidence of it. I just saw the reference, but I did not see any evidence in writing.

MS. PIROZZOLO: I'm sorry. There is no evidence that Dr. Gray sought or obtained consent.

THE COURT: Is it disputed?

MS. PIROZZOLO: I don't think as a matter of

admissible evidence it is disputed. I mean, Gatekeeper has made allegations that --

THE COURT: No. Is it disputed by you that he did not seek and obtain the consent for consultation?

MS. PIROZZOLO: Our position is he did not seek consent, and that is undisputed.

THE COURT: Undisputed in the sense there is no evidence of it one way or the other?

MS. PIROZZOLO: No, no, no, no. Sorry.

THE COURT: Is there something in writing? Is there some piece of evidence that I can look at that touches on this that you are aware of? I understand your position being no, there is not.

MS. PIROZZOLO: Well, the best evidence is, and I will try to get the cite, we asked Dr. Gray if he had sought and obtained consent, and he did not. He could not answer. You can read his answer. He says he thinks he told someone at some point.

THE COURT: Is that all there is in this case, that is what I guess I am getting at, in this record?

MS. PIROZZOLO: Well, you also have Dr. Roberts' testimony, which we cited. Dr. Roberts was a member of the Steering Committee and we cited his testimony where he says, in essence, he learned that Novartis had not been told about Gatekeeper and was surprised that had not been done and

understood why Novartis was upset about that.

THE COURT: That is not admissible, either. I should not say that. Gray's testimony is admissible for what it is worth, which is not very much, and this other Roberts testimony is not admissible at all. He heard that there was a problem and he was not surprised that Novartis was upset.

MS. PIROZZOLO: I know we submitted a Declaration from Dr. Sellers. I think he said he learned of the invention not until the Fall of 2009. I don't know if he specifically referenced when he learned of Gatekeeper.

THE COURT: It is not even a matter of learning of Gatekeeper. It is a more specific, for me, anyway, issue of when did he, if he did, seek and obtain the Committee's consent.

MS. PIROZZOLO: It's hard for us to prove a negative. It just didn't happen.

THE COURT: Well, so you say. There must be some proof of that or lack of proof; that is what I am getting at. The short of it is, you have told me what you know about it.

MS. PIROZZOLO: There is no record of it, no one has testified that it occurred. Even Dr. Gray, himself, didn't testify he obtained consent when asked.

THE COURT: Now, with respect to the research agreement involving Dana-Farber, that is no longer an issue, I take it, here. Is that right or not?

MS. PIROZZOLO: Yeah. Our point with that is really that by having these requirements of having people who are entering into potentially conflicting business relationships, by having the requirement that they notify the Steering Committee, you can avoid situations like this where there is disputes about who owns intellectual property, and those procedures weren't followed here.

THE COURT: Well, but the question I think is a more specific one: Is the option agreement a research support or collaboration agreement? You seem to have abandoned the theory that it was in respect of Dana-Farber.

MS. PIROZZOLO: Yes. Our theory really is that Gatekeeper has unclean hands or is not a bona fide purchaser of the option agreement because Dr. Gray was a shareholder of Gatekeeper, he was a founding shareholder. It's a small, closely held corporation. Clearly Dr. Gray knew he was supposed to obtain consent. He did not.

THE COURT: I just want to be sure that I am understanding what the issues are.

Now, with respect to the Materials Transfer Agreement, assume, as I think you have to, that I am going to treat that as some sort of physical transfer of something. Is there anything in here left for you in terms of material transfer?

MS. PIROZZOLO: There is.

THE COURT: Tell me what it is.

MS. PIROZZOLO: It was the crystallography studies that Dr. Eck performed using QAD-409. Those studies were physically provided to Dr. Gray's lab.

THE COURT: And that, as far as you are concerned, is material. I guess I have been conceiving the material in this setting as being physical and not studies, meaning physical stuff like QAD-409, that kind of thing.

MS. PIROZZOLO: Well, I don't think there is evidence of the actual material being transferred, you are correct. But Novartis transferred the material to Dr. Eck with an agreement that specifically said, This is for use in the collaboration and you can't --

THE COURT: Right, but he did not transfer physical material to someone else. He let studies be done under your theory, but he did not transfer some magic potion to someone else.

MS. PIROZZOLO: He transferred the results of the work he obtained.

THE COURT: And I just want to be sure that I am not missing something when I say the results are not within the scope of the MTA. I do not know how I could read the MTA that way. It talks in terms of unused material being destroyed, and that does not make any sense if we are talking about results.

MS. PIROZZOLO: Well, we are relying on paragraph 7 of the MTA, and it says, "[I]f in breach," and I'm excerpting a

bit -- it's on page 33 of our presentation -- "[I]f, in breach of this Agreement, the Materials are not solely used for the Studies..."

THE COURT: Well, it begs the question of what the materials are.

MS. PIROZZOLO: Well, and in this case --

THE COURT: It also talks about "unused material." "Any unused material will be destroyed under the applicant's supervision." That strikes me as being the physical things, physical, or chemicals or whatever.

MS. PIROZZOLO: I think, your Honor, if you take material that was provided to you under an MTA and then you create crystal structures of them, you are not free to just give other people those crystal structures without violating the MTA.

THE COURT: The crystal structures themselves?

MS. PIROZZOLO: Well, the information about the crystal structures.

THE COURT: See, that is the difference; it is derivative.

MS. PIROZZOLO: But I don't think you're free -- otherwise it would be very easy to circumvent an MTA.

THE COURT: No, it would not. No. The MTA serves a particular office, and the particular office is that physical substances will not be transferred. Now, there may be other

ways of controlling the passage of information in respect of the physical structures, but it is the physical structures that we are talking about in the MTA, I think, unless there is something more you would like to say about that.

MS. PIROZZOLO: Well, I don't think that's the way MTAs are understood, because otherwise --

THE COURT: The other thing that you would like to say is, "I do not agree with you."

MS. PIROZZOLO: Well, otherwise you get the structure, you look at it. You don't actually give someone the structure, but you tell someone everything you know about it so they can make it themselves, and basically that wouldn't be a violation of the MTA under your interpretation, and that that's a complete circumvention of the --

THE COURT: It is not entirely circumvention, because you have another set of agreements that are supposed to control it. Now we are talking about what I consider to be a very narrow agreement called a "Materials Transfer," because your interpretation would be I think quite generous in dealing with that.

I think we have reached an impasse with respect to that, unless there is something else.

MS. PIROZZOLO: Thank you, your Honor.

THE COURT: So, let me understand the position of Gatekeeper on these issues.

If I start with the patent application, and maybe even if I step back a bit and ask how come Dr. Eck got on the patent, what did he do to get on the patent?

MR. SCOTT: Well, I think he did two things. I think he, and as Dr. Gray readily admits, suggested the idea of doing a Jak3 irreversible inhibitor.

THE COURT: So, maybe that is conception, then, right?

MR. SCOTT: No, I don't think so, and I'll backtrack to that once I answer this first question.

THE COURT: Sure.

MR. SCOTT: The second thing he did which was of some significance was to do the crystallography of WZ-4002 with the T790M EGFR in September, October and November of 2008 after the reduction to practice. Those are the two things he did. And one could argue that that crystallography process was part of the reduction to practice.

THE COURT: Well, if you do, haven't you drawn him in, then, drawn Dr. Eck into a breach of his obligations under his funding from Novartis?

MR. SCOTT: I don't think simply drawing Dr. Eck into the invention --

THE COURT: I have been delicate. Has he breached it?

MR. SCOTT: No, I don't think so.

THE COURT: Why not? If he is using this set of techniques that he has developed as a result of funding from

Novartis to assist, as you said kind of secondarily maybe that is part of the reduction to practice, why isn't that included?

MR. SCOTT: But doing crystallography is what his Ph.D. is in. There is no evidence that the process of doing crystal structures has been derived from Novartis in any sense.

THE COURT: Crystal structures in this context with this set of materials and this set of compounds.

MR. SCOTT: But the work done in the Fall of 2008 didn't involve any Novartis materials; it was WZ-4002 and the T790M mutation. There was no Novartis materials then.

THE COURT: It does not necessarily have to be Novartis materials, and I guess it goes back to this question of "in part."

MR. SCOTT: Yeah, I would like to go back to that question.

THE COURT: Yes, go ahead.

MR. SCOTT: And I think we have done a lot of talking this afternoon about the patent. We are not here on a patent case; we are here on a contract case.

THE COURT: Well, but the patent case is an embodiment, as far as I can see, or can be looked at as an embodiment of the invention that is generated by the funding from Novartis, and so it becomes a stalking horse.

I was thinking of this in a different sort of way. Assume an appeal of whatever I do in this case. Where does it

go? I think it goes to the First Circuit, but I am not sure.

MR. SCOTT: I'm sure it does.

THE COURT: You are sure it does?

MR. SCOTT: Sure it does.

THE COURT: Any question on your part, Ms. Pirozzolo?

MS. PIROZZOLO: I think that's correct, your Honor.

THE COURT: So, in any event, I am interpreting patents in a contract setting. I think I have to. Why wouldn't I?

MR. SCOTT: Let me suggest why you don't.

THE COURT: All right.

MR. SCOTT: We are here on a contract claim. The contract deals with rights to program technology. "Program technology" is defined in the contract as technology. "Technology" is then defined as any invention, innovation or discovery, whether protectable by a patent or not and whether patentable or not, or copyrightable or any other form of trade-secret protection. The form of protection granted to the invention is irrelevant to its definition as "program technology."

THE COURT: I agree, except for this: That a core kind of invention will be one that is protected by a patent. Then we would not even be talking about whether we have an invention or an innovation or a discovery, because it is certifiably one of those; it is something that is protected by

a particular constitutional program.

MR. SCOTT: I agree. Let me just make one note. What we have here is a patent application; nothing has been issued yet.

THE COURT: Right.

MR. SCOTT: And it is protected by a patent, but it is protected with a number of other things in that patent. That patent is not limited to the invention. It has got other aspects to it.

THE COURT: So, let me go back to what I was saying about either 51 or 53. If I say, for purposes of providing metes and bounds of your authority, you can have everything except Claim 51 or Claim 53.

MR. SCOTT: I think if Claim 51 or 53 is the broad one that applies to all kinases and incorporates the more general definition, I agree. That is, what this case has been about from the very moment it was filed is mutant-specific irreversible inhibitors of T790M EGFR. That's the way the case was pled by Novartis, by DFCI and by Gatekeeper and that's how it has come to this Court. That's how it was defined -- the entitlement issue was initially raised by DFCI, and the entitlement issue was defined as --

THE COURT: What are you reading from now?

MR. SCOTT: This is from DFCI's motion for a Rule 16 case management filed June 27th. It's what initiated the

process that led us here today. The issue was to which party, Gatekeeper or Novartis, can and should Dana-Farber grant a license to the WZ-4002 intellectual property? That's what we have been fighting about all along.

And indeed in Novartis's opening brief on this motion, that's how they define the issue. They state at page -- their separate statement at fact number 136 is, "The '419 patent application describes and claims chemical compounds that inhibit the drug-resistant T790M 'gatekeeper' mutation of the EGFR protein and less effectively inhibit the wild-type EGFR protein. Among those compounds is WZ-4002."

That's their statement of undisputed facts at 136 and we didn't dispute it. That's what we are here about, not about all the many and varied other claims in that patent. So, the notion that they can claim, which we dispute, but even accepting that they can claim some rights to WZ-1-84, we don't care. They can have it. We are not interested in WZ-1-84 as a Jak3 inhibitor, which is all they have claimed any rights to.

And I can address whether or not, in view of that, we still have claims for interference. I think we still do, but that's not really before the Court here.

And I would also suggest, your Honor, that --

THE COURT: Why isn't it something I have to think about for present purposes under the Motions for Summary Judgment?

MR. SCOTT: Well, currently it's summary judgment on an issue, the entitlement issue. Nobody's done any discovery on the interference claims. We didn't take any depositions.

THE COURT: Because it is so inextricably intertwined with the question of damage. It is damage. That is what interference is.

MR. SCOTT: We have separated it, and we sit here today with it separated.

The other point I would make, and one of the problems of going down the approach suggested by Novartis is, if you accept their version of what they are entitled to based on the patent, Novartis would be entitled to every irreversible inhibitor that comes out of DFCI that inhibits any kinase, and that can't be. That brings them way violative of the Bayh-Dole Act. They can't tie up every irreversible inhibitor that comes out of DFCI.

And I would also suggest, your Honor, that any theory of the invention that fails to account for two things can't be right. One, the theory of the invention has to account for the delay between the May 30, 1997 invention or synthesis of WZ-4002 and the discovery 18 months later that, lo and behold, it has this mutant-specific irreversibly inhibitory effect on T790M. This notion of a straight-line series of inventions from Dr. Eck using QAD-409, et cetera, et cetera, et cetera; it doesn't make any sense, if that were the case, for WZ-4002 to

be synthesized and then to sit there for 18 months. The fact is, as Drs. Janne and Gray testified, that the library was built, it sat there. Dr. Gray didn't even think it was worth trying to test its mutant-specific inhibitors against T790M. It was Dr. Janne's idea in August and the invention was made in September of 2008.

The second thing that Novartis' theory can't account for, and this is on a more human scale than it is a science scale because I think probably the human scale is more informative, they can't account for the contemporaneous evidence of Dr. Janne's and Dr. Gray's surprise and excitement in September of 2008 that, lo and behold, we've hit upon something. If it is as Novartis suggests, that should have been obvious to them months prior, but it wasn't and the contemporaneous evidence proves it wasn't.

THE COURT: I understand your resistance to the use of the patent as a prism to refract light on this dispute, but let us assume that, surprise to the contrary notwithstanding, they claimed it in Claim 1.

MR. SCOTT: "It" being?

THE COURT: "It" being the mutant-specific effect of inhibition that you find from WZ4002 on T790, is it? I am losing the numbers.

MR. SCOTT: Yes. Assume they claimed it in Claim 1.

THE COURT: It is said to be a genus claim, covers all

kinds of things in this area, it is not just specific, and so they had no idea how many things, how many species there were in this genus.

MR. SCOTT: Again, I don't think that the claim-by-claim analysis of the patent is the right approach. I think it's an invention-by-invention analysis. And if, in fact, they made that claim in Claim 1, then I think this Court should issue an order that Gatekeeper is entitled to that invention and then deal with the application however it needs to be dealt with in order to get us the invention we are entitled to.

I think the entitlement issue comes first, so then we will deal with the patent application.

THE COURT: Well, but the question is what you are entitled to, and they are making this argument, which I had said was ethereal and still has certain of those qualities as I listened to it, but it is pretty broad and it covers a lot of territory, and the question for me is how properly to construe a contract that purports to convey something that is mirrored in the claims of the patent. That is the issue that I am trying to deal with. I suppose I could ignore it altogether and say that is a patent that does not have anything to do with this case. I am not sure I want to do that.

MR. SCOTT: But I think it is the case, your Honor, that it is common in industry to carve up a patent and to

license specific rights that are subparts of a patent, and all we are entitled to is a license. We don't care whether it's the whole patent or whether it's a subset.

THE COURT: I understand that. The issue here is they claim they are entitled to it too, and they claim that they are entitled to it with priority over you. That is why it is in a peculiar posture. I am dealing with a series of analogies, but this is a priority case.

MR. SCOTT: I think the analogies are dangerous, because I don't think it's a priority case, and I think that they are claiming different parts of that patent. They are claiming that they have some rights to the invention of WZ-1-84 as a Jak3 inhibitor, and they are saying, Oh, well, we find that in the patent, and therefore we are entitled to the whole patent.

But that is not the analysis that the CRA demands that we and this Court undertake. It's not a question of who is the inventor and who has priority of a patent. It's a question of who has rights of program technology under the CRA, and if that program technology happens to be bound to other kinds of technology in a patent, that's of no moment under the CRA. It's a question of who has rights to the invention.

And I think the invention here has been defined from the outset: mutant-specific irreversible inhibitors of T790M.

THE COURT: All right.

MR. SCOTT: If I can -- actually, I don't know if it's worthwhile -- I can respond to some of the points.

THE COURT: Go ahead, please.

MR. SCOTT: I think there are some dangers, actually, in a PowerPoint presentation and parts of evidence taken out of context, so I'd urge the Court actually to look at the underlying exhibits.

THE COURT: I am sure you recognize that that is what I have been trying to do.

MR. SCOTT: One of the first slides that we saw was a quote, "Irreversible inhibitors, as a class, overcome resistance." That was in that presentation. I would like to remind the Court that the efficacy of irreversible inhibitors against the T790M mutation was described in the very first article announcing the discovery of the T790M mutation, and Dr. Janne testifies to that. So, Dr. Eck was not making a revolutionary or even a new suggestion. Counsel suggested, Oh, gee, that's preceded by just a few pages with a crystallization structure of QAD-409 and suggests that there was a connection between the two.

If you look at Dr. Eck's testimony about what that Exhibit 90 is, and we cite to it in our papers, it's a presentation of two different presentations: One, here's how we developed a Jak3 irreversible inhibitor; and, two, here's our discovery about the T790M means of resistance. And to

combine those two presentations the way it was suggested earlier I don't think is a fair characterization of the document.

Dr. Eck's testimony about locating the place where binding can occur, that was testimony regarding the development of, again, a Jak3 inhibitor.

Counsel quoted from the testimony of Dr. Zhou about QAD-409 being the basis. That was at page 24 of Dr. Zhou's testimony. And I would like to, if you just continue down that page at line 21: "Okay."

THE COURT: Where is he in the-

MR. SCOTT: I think it's the last tab. I don't know. Do they go to F? I think it's F.

MS. PIROZZOLO: Exhibit F.

MR. SCOTT: Exhibit F. I have tabbed mine by names.

THE COURT: F is Timothy Scott.

MR. SCOTT: I'm sorry. It's probably not so important a point to take up all this time.

THE COURT: Well, you mentioned it so I am trying to read all of the deposition testimony.

MR. SCOTT: I appreciate it. It's not as bad as it could be.

THE COURT: Pardon me?

MR. SCOTT: It's not as bad as it could be.

THE COURT: It never is, in my experience. But go

ahead.

MR. SCOTT: Page 24, line 21. The quote that counsel quoted was from lines 1 to 8. I would like to continue. Actually, you can pick it up at line 12.

"Okay. At the top it says 'Strategy for identification of mutant-selective irreversible inhibitors of T790M mutant EGFR." That's us.

Answer: "Uh-huh."

"Okay. And then at the bottom it lists some more of your compounds. Do you see?"

"Yes."

"WZ3146, 4002 and WZ8040."

"Yes."

"Okay. Were you involved in the strategy for identification of mutant-selective irreversible inhibitors?"

"Yes, I was."

"Please describe the strategy."

"So, based on the pyrimidine," which is different than a purine; the QAD-409 is a purine," based on the pyrimidine... I made several -- several compounds. And so we actually -- Dr. Gray published a paper about EGFR/Bmx cross-reactivity. So we collaborated with Dr. Pasi Janne's lab to test those compounds. Then after -- after we got the results, we redesigned and remake more compounds to optimize the properties of our compounds."

He later testifies this was the process that took place in September 2008. It has little or nothing to do with QAD-409 or WZ-1-84. Counsel pointed out that WZ-1-84 appears in the patent except for I guess there's only one little difference, there's this chlorine molecule. Well, in the world of chemistry a little chlorine molecule is a significant thing.

THE COURT: It is like, as Mark Twain said, There is a big difference between fire and a firefly.

MR. SCOTT: Yes.

Finally, the issue of whether Dr. Gray sought consent, Dr. Gray addresses that issue at page 35 of his testimony.

THE COURT: Which is?

MS. PIROZZOLO: D.

MR. SCOTT: Tab D, I'm told.

THE COURT: And the page again?

MR. SCOTT: Page 35, beginning with line 16:

"Okay. Do you have any recollection of whether you informed the steering committee that you were founding Gatekeeper before you, in fact, found Gatekeeper?"

"I can't remember the time in between when I talked to the steering committee, Livingston and Roberts, about founding that, vis-à-vis when the company was started."

So, what he says is, I talked to them, but I can't put it before or after the founding.

THE COURT: But that is not all of what he is supposed

to do. It is supposed to be in writing, isn't it?

MR. SCOTT: I don't think so, because if you consult the testimony of Dr. Roberts, and that is at pages 7 and 8, the questions and answers go as follows: Question:

THE COURT: Just a moment.

MR. SCOTT: Sorry.

THE COURT: I want to be sure I am picking up everything here.

MR. SCOTT: Question: "Is there a mechanism for a principal investigator to bring matters to the attention of the steering committee -- "

THE COURT: Hold on just a second. I am going back and forth between things.

MR. SCOTT: Sorry.

THE COURT: Roberts is which one, which tab?

MS. PIROZZOLO: Tab E, your Honor.

THE COURT: And the page number again?

MR. SCOTT: 7 to 8.

Question: "Is there a mechanism for a principal investigator to bring matters to the attention of the steering committee?"

Answer: "Yes."

Question: "Can you describe that mechanism for me, please."

Answer: "It's informal. But in general, a PI would

contact either...Dennis Lynch, who acts as David's lieutenant, as it were, and is more involved in the day-to-day interaction with Novartis than either David or I am."

Question: "And once an issue was brought to the attention of Dr. Livingston, you, or Dr. Lynch, who would be responsible, then, for following up and bringing it to the attention of the full steering committee?"

"This, again, is an informal process and it could happen in several ways. It could happen via a communication between either myself or David -- more likely David -- and Bill Sellers. But the most likely means would be for Dennis Lynch to contact...Phil Gotwals, Bill Sellers' lieutenant."

The point is that Dr. Gray brought this to the attention the way people had operated under that CRA throughout, which is by --

THE COURT: Well, that may be the way they operate, but Section One of the Agreement says that you inform them and obtain prior written approval from the steering committee to enter into an arrangement, and I take it that there is no evidence of a prior written --

MR. SCOTT: No, there is not.

THE COURT: So, what you are saying is there is a custom and practice that has effectively put a gloss on this prior written approval.

MR. SCOTT: Yes. And I would add to that, your Honor,

that the addendum of the Dana-Farber terms to that Consulting Agreement expressly provide that nothing in the Consulting Agreement shall give Novartis any rights in any invention or even any priority towards any rights to any invention. So, whatever the significance of the Consulting Agreement vis-à-vis Dr. Gray personally, it doesn't have significance with respect to granting rights to Novartis to any invention made at Dana-Farber.

THE COURT: So, it is immaterial in this setting?

MR. SCOTT: Yes.

THE COURT: All right. I understand that.

MR. SCOTT: Thank you.

THE COURT: Ms. Pirozzolo, anything else you want to add?

MS. PIROZZOLO: Yes, your Honor, I would like to respond briefly. The first point: I really do think you have to look at the patent application at issue to define "program technology," and that is because the dispute here is was Novartis guilty of tortious interference by virtue of asserting rights --

THE COURT: Let me pause. I had not thought to go back to either the Complaint or the Rule 16 statement, but do you dispute that we are dealing with entitlement to mutant-specific inhibitors?

MS. PIROZZOLO: That is included in the invention,

but, for example, one issue -- Gatekeeper appears to concede that Novartis funded work on Jak3 inhibitors that are included in this patent application. If that is the case, how could we have tortiously interfered by virtue of asserting rights to license at least those inventions?

THE COURT: Well, see, I think it is the case that I am limited on this Motion for Summary Judgment to the question of entitlement; that is to say, the issue here is not whether you interfere but who is entitled to what, and if I substantially constrain that entitlement under these circumstances, if I substantially constrain your entitlement under those circumstances, then we move on to this question of interference.

I do not know whether you interfered or not. I am not really being asked to say that yet. You are apprehensive that you might have, that is why you brought a declaratory judgment action, and to the degree that I have to decide this as a declaratory judgment action prudentially, that is, I have discretion not to deal with things that are not cases in controversy, as I assume there is a real issue about interference.

MS. PIROZZOLO: Well, our declaratory judgment action is now moot because we have ceded the rights to the invention. So, the only claim as a defendant on the tortious interference claim --

THE COURT: The question of interference is not directly before me.

MS. PIROZZOLO: Well, except the elements of tortious interference include did they have a contract, and if we had rights in this patent application then we had prior rights and they didn't have rights. So, entitlement would resolve the tortious interference claim, and it's our position that it does.

THE COURT: Well, if you prevail on it, it will. If you do not prevail on it, then we move on to the question of the nature of interference and damages associated with it.

MS. PIROZZOLO: Well, except if your Honor finds I believe that we were entitled to part of the patent application, which I sense is a possibility, then clearly we were entitled to part, so we couldn't have tortiously interfered by virtue of asserting that right --

THE COURT: I do not know the answer to --

MS. PIROZZOLO: -- and that should dispose of the claim against us.

THE COURT: It should, but it does not do it on this Motion for Summary Judgment. It becomes a second Motion for Summary Judgment, I suppose.

MS. PIROZZOLO: But, your Honor, the thing that was being licensed here, the subject of the option agreement was a patent application. So, the issue is whether Dana-Farber had

to offer it to us.

THE COURT: No. It was an invention, It was not the patent application. It was an invention or discovery or something like that.

MS. PIROZZOLO: Well, except that the operative provisions of the Collaboration Agreement are that we have a right to an option to license program technology.

THE COURT: Right, but that license could proceed from a patent or from any of a number of forms of protected or intellectual property. It may not be a patent. Whether or not protected by patent, copyright or trade secret law or otherwise.

I am not foreclosing the idea that the patent is the cat's paw for whatever intellectual property is involved here and it is the proper way for me to conceive it and provide a definition, but it does not get incorporated by reference immediately. That is the point, I guess.

MS. PIROZZOLO: I guess I think the problem you have if you don't look at it as a patent is what is supposed to happen when Dana-Farber files a patent application. In our view, what is supposed to happen is, if we funded any of the inventions in that they have to offer it to us to license under the CRA. That's kind of the point of all those provisions.

THE COURT: Not to play too much on current events, but this is the Ronald Reagan, "It is my microphone, so I get

to use it."

MS. PIROZZOLO: Well, the other thing is, your Honor, the fire/firefly example you used, Gatekeeper has made a big point of, well, these are pyrimidines, not purines, but the compound that I pointed you to in Table 1 is a purine. That's our point, is, this patent application is covering a lot of technology.

THE COURT: I do not treat I guess it was Dr. Zhou's testimony as being conclusive on that issue, whether he professed to having some lack of recollection with respect to this, certain aspects of this.

MS. PIROZZOLO: But all I'm pointing out is you can look at the patent application and you can see that the compounds include both pyrimidine --

THE COURT: Like the deposition transcript, I will look at the patent application.

MS. PIROZZOLO: -- and purine compounds.

And I just wanted to point out, when you asked the question about Dr. Eck's role in the invention, the answer was the ideas provided and then work done after reduction to practice, which I don't think qualifies as an inventive contribution. So, Dr. Eck did something here.

THE COURT: Well, what is the impact of that? Let us assume that three people who work together closely decide for various interpersonal relations that they will announce that

the three of them are the inventors. Now, I suppose I can use that as a form of impeachment that Dr. Eck must have done something to do that. On the other hand, maybe they felt strongly about their relationship and so they decided, We'll make all three of us joint inventors under these circumstances. What is it to you?

MS. PIROZZOLO: Well, actually I think we mention this in our papers, but Dr. Eck testified that he found out about the patent application accidentally. Dr. Gray had been taking a lead in the patent application. He filed the patent application without Dr. Eck on it. Dr. Eck then got in touch with the patent attorney and explained his role in the invention and was added as an inventor.

THE COURT: But when he provided the explanation we do not have his testimony of his explanation of what he did that ties it to Novartis funding, do we?

MS. PIROZZOLO: Well, we have cited his testimony about his work on conceiving this class of compounds as part of his Novartis-funded research project in 2005 and 2006 --

THE COURT: Right.

MS. PIROZZOLO: -- and that he communicated that idea to Dr. Gray.

THE COURT: But we are back to conception and reduction to practice. That is the point. I think it is a terrific jury argument. I am not sure it does very much on

summary judgment that you have got some uncertainty about who the inventor is and what the contributions or relative contributions of the inventors are, even when the inventors have their own explanations of what they are.

MS. PIROZZOLO: Well, for summary judgment we are relying on evidence of what Dr. Eck provided with regard to the development of these compounds, not the mere fact that he was added as inventor. I was just responding to your comment. Maybe they are just buddies and he got thrown on the patent application because they're friends and they thought that was the collegial thing to do. The evidence actually suggests otherwise.

THE COURT: All right.

MS. PIROZZOLO: Thank you, your Honor.

THE COURT: Anything else?

MR. SCOTT: Your Honor, two more things. Ten seconds.

We don't concede on WZ-1-84; we don't think it's Novartis-funded. I could get into that, if you like, but since we are running out of time, the second thing is, there were objections made to some of the evidence we submitted. I can address that.

THE COURT: As I presently conceive what I am going to be doing with this, and I have done a certain amount of work, I do not think that the evidentiary objections are going to make a difference.

MR. SCOTT: Okay. I have responses I can hand up to the Court, if you want to read them, but, in essence, they say they are all admissions and under the revised Rule 56, the question is not --

THE COURT: You can paper the record. Submit it in the ordinary course is all I would say with respect to that.

MR. SCOTT: Okay. Thank you, your Honor.

THE COURT: Thank you. So, we will be in recess in this matter.

THE CLERK: All rise.

(The Honorable Court exited the courtroom at 4:00 p.m.)

(WHEREUPON, the proceedings adjourned at 4:00 p.m.)

C E R T I F I C A T E

I, Brenda K. Hancock, RMR, CRR and Official Reporter of the United States District Court, do hereby certify that the foregoing transcript constitutes, to the best of my skill and ability, a true and accurate transcription of my stenotype notes taken in the matter of *Dana-Farber Cancer Inst. v. Gatekeeper Pharmaceuticals, Inc., et al.*, No. 1:10-cv-11613-DPW.

Date: January 19, 2012

/s/ Brenda K. Hancock

Brenda K. Hancock, RMR, CRR

Official Court Reporter